K042252

DEC - 6 2004

SIERRA™ Femoral Hip Stem
510(k) SUMMARY
August 2004

I. **Company**: Nexmed, Inc.
6110 Corte Del Cedro
Carlsbad, CA 92009, USA
(760) 431-9286

II **Contact Person**: Ellen Yarnall, Director of Regulatory Affairs

III **Trade/Proprietary Name**: SIERRA™ Femoral Hip Stem

IV **Product Description**:

The SIERRA™ Femoral Hip Stem is a sterile component used to help restore patient range of motion and aid in the treatment of other deformities as listed in the *Indications for Use*. The SIERRA™ Femoral Hip Stem has a tapered distal stem design and is available in a variety of options including cemented, porous coated or porous coated with hydroxylapatite (HA) coating. They are also available with standard or high offset necks, as well as collared and non-collared designs. This submission seeks clearance for the SIERRA™ Femoral Hip Stem, which is a line extension to the NexFlex™ Total Hip System. The SIERRA™ Femoral Hip Stem is manufactured from titanium alloy (Ti 6Al-4V, ASTM F136) or cobalt chrome (CoCrMo, ASTM F75). Cobalt chrome stems are intended for cemented use. The porous coated and HA/porous coated stems are intended for uncemented use.

V. **Classification**

LPH (21 CFR 888.3358)	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
JDI (21 CFR 888.3350)	Hip joint metal/polymer semi-constrained cemented prosthesis
KWY (21 CFR 888.3390)	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented or uncemented prosthesis.

VI **Indications for Use**

1) When used as a hemi-hip replacement system, it is intended for osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal involvement of the corresponding acetabulum, femoral head or neck fractures, aseptic necrosis of the femoral head, previous failed hip arthroplasty where there is evidence of sufficient bone quality to adequately set the implant.

2) When used as a total hip replacement system, it is intended for osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal involvement of the corresponding acetabulum, femoral head or neck fractures, aseptic necrosis of the femoral head, previous failed hip arthroplasty where there is evidence of sufficient bone quality to adequately set the implant.

3) In addition, the SIERRA™ hip stem is intended for cases where alternative modes of treatment appear less preferable and the associated risks of a total hip replacement are thought to be acceptable. It is intended for severely disabled joints, which could result from arthritis or late stages of avascular necrosis and revisions of unsuccessful acetabular cup arthroplasty and/or femoral procedure.

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VII **Substantial Equivalence:**

The SIERRA™ Femoral Hip Stem is substantially equivalent to femoral hip stems from the following predicate devices:

Trade/Proprietary Name	Manufacturer	Clearance
NexFlex™ Total Hip System	Nexmed, Inc.	K033580
Synergy HA Coated Porous Femoral Stems	Smith & Nephew, Inc.	K002996
Synergy Cemented Hip Stems	Smith & Nephew, Inc.	K990369

VIII **Performance Data:**

Mechanical and dynamic testing of the SIERRA™ Femoral Hip Stem was performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2004

Ms. Ellen A. Yarnall
Director of Regulatory Affairs
Nexmed, Inc.
6110 Corte Del Cedro
Carlsbad, California 92009

Re: K042252
Trade/Device Name: Nexflex Total Hip System, Sierra Femoral Hip Stem
Regulation Number: 21 CFR 888.3358; 21 CFR 888.3350; 21 CFR 888.3390
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; Hip joint metal/polymer semi-constrained cemented prosthesis; Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: LPH, JDI, KWY
Dated: November 15, 2004
Received: November 16, 2004

Dear Ms. Yarnall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

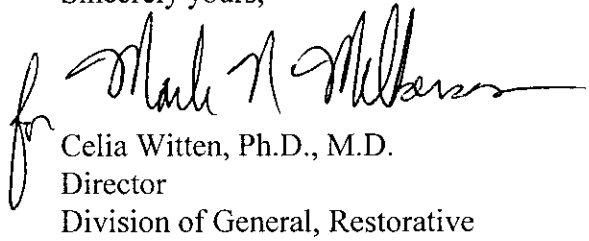
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042252

Device Name: SIERRA™ Hip Stem

Indications for Use:

1) When used as a hemi-hip replacement system, it is intended for osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal involvement of the corresponding acetabulum, femoral head or neck fractures, aseptic necrosis of the femoral head, previous failed hip arthroplasty where there is evidence of sufficient bone quality to adequately set the implant.

2) When used as a total hip replacement system, it is intended for osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal involvement of the corresponding acetabulum, femoral head or neck fractures, aseptic necrosis of the femoral head, previous failed hip arthroplasty where there is evidence of sufficient bone quality to adequately set the implant.

3) In addition, the NexFlex™ Total Hip System is intended for cases where alternative modes of treatment appear less preferable and the associated risks of a total hip replacement are thought to be acceptable. It is intended for severely disabled joints, which could result from arthritis or late stages of avascular necrosis and revisions of unsuccessful acetabular cup arthroplasty and/or femoral procedure.

for Mark N Milhous

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K042252

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)